IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, v. MURTY VEPURI; ASHVIN PANCHAL; AND KVK-TECH, INC.	**ORAL ARGUMENT REQUESTED** Criminal No. 21-132 Hon. Harvey Bartle, III

DEFENDANT ASHVIN PANCHAL'S
MOTION TO DISMISS THE SUPERSEDING INDICTMENT

Pursuant to Federal Rule of Criminal Procedure 12(b), Defendant Ashvin Panchal, through counsel, respectfully moves this Court for an order dismissing the Superseding Indictment (Dkt. 4) for failure to state an offense against Mr. Panchal and as being barred by the statute of limitations as a matter of law. In support of this Motion, Mr. Panchal relies on the attached Memorandum of Law, which is herein incorporated by reference. Mr. Panchal respectfully requests oral argument on this Motion.

WHEREFORE, Mr. Panchal respectfully requests that the Court dismiss the Superseding Indictment in its entirety as to Mr. Panchal.

Respectfully submitted,

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December 1, 2021

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DEFENDANT ASHVIN PANCHAL'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS THE SUPERSEDING INDICTMENT

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I. INTRODUCTION AND SUMMARY

More than fourteen years ago, KVK-Tech, Inc. ("KVK")—a generic pharmaceutical company based in Newtown, Pennsylvania—obtained approval from the Food and Drug Administration ("FDA") to distribute Hydroxyzine Hydrochloride ("Hydroxyzine"), a drug used to treat anxiety and tension. Some time after KVK obtained FDA approval, KVK learned that the FDA-approved manufacturer of the active pharmaceutical ingredient ("API") for Hydroxyzine—a Belgian company named UCB, S.A. ("UCB")—decided to delegate initial manufacturing of the material for the API to an FDA-registered facility in Mexico owned and operated by a UCB subcontractor named Dr. Reddy's Laboratories ("Dr. Reddy's").[1] UCB provided FDA with advance notice of the change. In 2013, the FDA raised concerns with KVK's use of UCB API with material from Dr. Reddy's. The FDA took the position that KVK needed pre-approval to use the API because Dr. Reddy's was not listed as a manufacturer in KVK's original Abbreviated New Drug Application ("ANDA") for Hydroxyzine. The FDA conducted an inspection of KVK through which it learned virtually all of the material facts relating to KVK's use of Dr. Reddy's material, and it ultimately decided not to take any administrative enforcement action against KVK or its co-Defendants, Ashvin Panchal ("Mr. Panchal") and Murty Vepuri ("Mr. Vepuri").

Almost eight years later, on June 10, 2021, the Government filed a Superseding Indictment ("Indictment") arising out of the same conduct that the FDA declined to prosecute in 2013. The Indictment charges Defendants with conspiring to defraud the FDA and to commit an

[1] If this case proceeds to trial, the evidence would show that Dr. Reddy's manufactured the material according to UCB's specifications, the material was tested, released, and shipped to customers by UCB from Belgium at the final step of the manufacturing process, and UCB, KVK, and FDA testing assured that the final API was safe and effective.

offense against the United States in violation of 18 U.S.C. § 371. Specifically, the Government alleges that Defendants conspired: (i) to distribute an "unapproved new drug" (i.e. Hydroxyzine formulated using UCB API with material from Dr. Reddy's) in violation of FDA regulations; and, subsequently, (ii) to make false statements or misrepresentations to the FDA about how those alleged regulatory violations occurred. The Government's theory of the case hinges entirely upon the allegation that KVK was required to obtain pre-approval from the FDA to use API with material from Dr. Reddy's facility in Mexico. But the Government is wrong as a matter of law. KVK was not required to obtain pre-approval or notify the FDA about UCB's decision to use a new subcontractor, particularly where UCB already informed the FDA of the change, the change was incorporated by reference in KVK's previously-approved ANDA for Hydroxyzine, and UCB remained the manufacturer of record for the API. KVK's approval to distribute Hydroxyzine could not have simply evaporated upon its failure to file essentially a duplicate notice of UCB's subcontracting change. Even if KVK was required to file such paperwork, a technical reporting violation would not have transformed KVK's approved Hydroxyzine into an "unapproved new drug." The FDA itself essentially acknowledged as much, as it decided not to take any administrative action against Defendants at the relevant time despite knowledge of the material facts. Thus, as the object of the alleged conspiracy was not unlawful, the charges cannot stand.

The charges against Mr. Panchal are also barred by the applicable five-year statute of limitations. The Indictment alleges that Mr. Panchal and his co-Defendants conspired to defraud the FDA and to distribute an "unapproved new drug" in the time period of April 2011 through December 2013, and subsequently attempted to conceal that past conduct from the FDA through a handful of actions or omissions in 2014 and 2015. But subsequent acts taken to conceal a

conspiracy that has already achieved its objective cannot extend the statute of limitations. Thus, the statute began running in December 2013, when the central objective of the alleged conspiracy—the distribution of Hydroxyzine using API with material from Dr. Reddy's—was accomplished. The Indictment, however, was not filed until June 10, 2021, almost three years after the statute expired in December 2018. The Indictment is therefore untimely on its face and should be dismissed.

Even if the Court considers the charged conduct as part of a single conspiracy extending past December 2013, which it should not, the charges against Mr. Panchal are still time barred. The last possible overt act in furtherance of the alleged conspiracy occurred on November 20, 2014. Thus, that is the latest possible date on which the statute began running. Although the Government may be entitled to some period of tolling under 18 U.S.C. § 3292 because it made a request for evidence from a foreign government, it is entitled to no more than six months of tolling because the foreign government took final action on the request before the statute would have otherwise expired. Thus, the statute of limitations in this case ran as to Mr. Panchal no later than May 20, 2020 (five years and six months after the last possible alleged overt act). Although Mr. Panchal signed a tolling agreement (on June 8, 2020), he did not do so until almost one month after the statute expired. Thus, the tolling agreement is ineffective, and the charges are time barred. The Court should dismiss the Indictment in its entirety as to Mr. Panchal.

II. BACKGROUND

A. Regulatory Background

A drug manufacturer seeking to market and distribute a generic drug in the United States must first obtain approval from the FDA by filing an Abbreviated New Drug Application (ANDA) with the FDA. Dkt. 4 at 3 ¶ 8. Among other things, the ANDA must identify the manufacturer of the active pharmaceutical ingredient (API) for a drug. *Id.* at 4 ¶ 10. In some

cases, a generic drug manufacturer may obtain API from a third party manufacturer, as opposed to manufacturing the API itself. In such a situation, the FDA allows that third party to maintain the confidentiality of its manufacturing processes by submitting a "drug master file" ("DMF") to the FDA with the necessary information about the API. *See* 21 C.F.R. §§ 314.420(a) & 314.430(a). A generic pharmaceutical manufacturer seeking approval to distribute a new drug may incorporate the third party's DMF by reference in its ANDA. An ANDA is deemed to include "all data and information . . . incorporated by reference in the [ANDA], including . . . drug master files." *Id.*

After an ANDA is approved, a generic manufacturer may market and distribute the drug unless and until the FDA withdraws approval. *See Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 633 (1973). After approval, certain changes from the ANDA may require further FDA approval or notification. *See* 21 C.F.R. § 314.70(a) (stating that a drug maker "must notify FDA about each change in each condition established in an approved NDA beyond the variations already provided for in the NDA"). FDA guidance has addressed when manufacturing site changes qualify as "a condition established in an approved NDA," and thus FDA notification is required, explaining that manufacturing sites in this category are those "owned by the applicant or contract sites used by the applicant." FDA, Guidance for Industry: Changes to an Approved NDA or ANDA, at 8 (2004). That portion of the guidance does not apply to the instant case because Dr. Reddy's was neither a site "owned" by KVK, nor a "contract site" of KVK. Indeed, KVK had no direct relationship with Dr. Reddy's. The guidance does not address the situation at issue in this case: i.e. whether FDA notification is required when a pharmaceutical company obtains API from the same manufacturer but that manufacturer has added a new contract site and has informed FDA of the change.

B. Factual and Procedural Background

In 2006, KVK—a generic pharmaceutical company based in Newtown, Pennsylvania—submitted an ANDA to manufacture Hydroxyzine, a prescription drug used to treat anxiety and tension. Dkt. 4 at 1 ¶ 1. The FDA approved KVK's ANDA the following year. *Id.* at 1 ¶ 2. As relevant here, KVK identified Interchem, Inc. ("Interchem") as the supplier of the API for Hydroxyzine, and UCB, a Belgian company, as the manufacturer. KVK incorporated UCB's DMF by reference in its ANDA, and the ANDA was approved on that basis. *See id.* at 4-5 ¶ 12. At the time the ANDA was submitted, UCB manufactured the API for Hydroxyzine at its own FDA-registered facility in Belgium.

In 2008, UCB decided to shift initial manufacturing of material for the API for Hydroxyzine from its own facility in Belgium to a subcontractor in Mexico, Dr. Reddy's Laboratories. Dr. Reddy's manufacturing site was FDA-registered, and it produced the material according to the specifications and processes set forth in UCB's DMF. Moreover, the material produced by Dr. Reddy's did not make its way directly to customers. Instead, it was shipped to UCB in Belgium, where UCB performed testing and quality assurance to determine whether to release and ship the API under the UCB label to its customers. All of these final manufacturing steps were performed in Belgium. UCB provided advance notice to the FDA of its decision to change manufacturing sites via an update to its DMF, which is the same DMF that KVK had incorporated by reference in its ANDA.

In 2010, KVK ordered API for Hydroxyzine from its supplier Interchem. *Id.* at ¶ 1. Interchem obtained the API from UCB, which, as noted above, had subcontracted the initial manufacturing steps to Dr. Reddy's in Mexico. KVK received shipments of the API in January, March, and May 2011. *Id.* at 8 ¶¶ 2, 4.

In June 2011, the FDA issued a warning letter to Dr. Reddy's in connection with alleged regulatory violations at its Mexican facility. *Id.* at 9 ¶ 7. The FDA issued an import alert the following month. *Id.* at 9 ¶ 8. The warning letter did not mention Hydroxyzine, and KVK was unaffected by the import alert because all of its imports of Dr. Reddy's material occurred before the import alert was issued. The import alert was ultimately lifted in July 2012. *Id.* at 5-6 ¶ 15. KVK tested the API it received to ensure that it was safe and met all applicable specifications, and its testing confirmed the safety and efficacy of the API. KVK distributed 62 batches of Hydroxyzine over the course of the next two years, from April 2011 through December 2013, using API from UCB with material that originated at Dr. Reddy's. *Id.* at 9-10 ¶¶ 8-9.

In June 2013, the FDA detained a shipment of Hydroxyzine API that was in transit to KVK. *Id.* at 10 ¶ 10. The stated reason for the detainment was that KVK's ANDA for Hydroxyzine did not reflect Dr. Reddy's as the manufacturer of the API. The FDA thereafter conducted an inspection of KVK's facilities in which it raised concerns about KVK's use of material that originated at Dr. Reddy's facility in Mexico, even though that material had been tested and shipped from UCB in Belgium and met all technical specifications. *Id.* at 11-12 ¶ 14. The Government alleges that Mr. Panchal—then the Director of Quality Assurance for KVK—made various misleading statements to the FDA about the circumstances surrounding KVK's use of material originating from Dr. Reddy's during this time period. *Id.* at 10-13 ¶¶ 11-14. In an abundance of caution, KVK decided to issue a voluntary recall of Hydroxyzine manufactured using material originating from Dr. Reddy's in December 2013. *See* FDA, Enforcement Report – Week of Jan. 29, 2014 (last visited Nov. 18, 2021), https://www.accessdata.fda.gov/scripts/ires/index.cfm.

The FDA conducted another inspection of KVK's facilities in the time period of November 17, 2014 through December 11, 2014. Dkt. 4 at 13 ¶ 18. Despite having learned virtually all of the relevant facts surrounding KVK's use of UCB material that originated in Mexico, the FDA did not issue a warning letter or take any administrative enforcement action against Defendants in response to the distribution of Hydroxyzine using API with material that originated at Dr. Reddy's facility.

Nevertheless, on June 10, 2021, more than ten years after KVK allegedly began carrying out its scheme to distribute an unapproved new drug, *see id.* at 7 ¶ 1, the Government filed the instant Indictment against Defendants Panchal, Vepuri, and KVK. As relevant here, Mr. Panchal was charged with one count of conspiracy in violation of 18 U.S.C. § 371. The conspiracy charge is based on: (i) an alleged conspiracy to impede, impair, and defeat the lawful functions of the FDA in ensuring that drugs marketed and distributed in the United States are safe and effective for their intended uses; and (ii) an alleged conspiracy to commit an offense against the United States by: (a) introducing unapproved drugs into interstate commerce in violation of 21 U.S.C. §§ 331(d) and 355(a), and (b) by making material false statements and misrepresentations to the FDA in violation of 18 U.S.C. § 1001.

III. LEGAL STANDARD

Under Federal Rule of Criminal Procedure 12(b)(3), a district court may review the sufficiency of an indictment "to ensure that legally deficient charges do not go to a jury." *See United States v. Huet*, 665 F.3d 588, 595 (3d Cir. 2012). When assessing a motion to dismiss the indictment, the court must determine whether "the facts alleged in the indictment, if accepted as entirely true, state the elements of an offense and could result in a guilty verdict." *See United States v. Bergrin*, 650 F.3d 257, 268 (3d Cir. 2011). Federal Rule of Criminal Procedure

12(b)(3) authorizes dismissal if the allegations in an indictment "do not suffice to charge an offense." Although the alleged facts are assumed to be true, the indictment must allege "more than just the essential elements of the offense." *See United States v. Vitillo*, 490 F.3d 314, 321 (3d Cir. 2007).

IV. ARGUMENT

A. The Indictment fails to state an offense against Mr. Panchal because the charges depend on alleged underlying regulatory violations that do not exist.

The Government's entire theory of the case rests on a flawed premise: that KVK violated FDA regulations when it did not obtain pre-approval to distribute Hydroxyzine manufactured with API obtained from UCB with material that originated at Dr. Reddy's facility in Mexico. *See* Dkt. 4 at 5 ¶ 13. As set forth in KVK's contemporaneously-filed Motion to Dismiss—which Mr. Panchal hereby incorporates by reference—and as summarized below, the Government is wrong as a matter of law. KVK's alleged conduct, taken as true for purposes of this Motion to Dismiss, did not violate any regulatory requirements. Moreover, even if KVK did commit a technical reporting violation, that would not have transformed its approved Hydroxyzine into an unapproved new drug. The Government's case against Mr. Panchal cannot stand in the absence of those alleged regulatory violations because, to state a conspiracy charge, the Government must be able to allege, *inter alia*, "the existence of an agreement to achieve an ***unlawful*** objective." *United States v. Rigas*, 605 F.3d 194, 206 (3d Cir. 2010) (en banc) (emphasis added). It has not done so, and cannot do so, here. The Indictment should therefore be dismissed.

As set forth more fully in KVK's Motion to Dismiss, there are at least four reasons why no crime occurred under the facts alleged in the Indictment as a matter of law: (1) UCB's decision to change manufacturing sites to a subcontractor, Dr. Reddy's, did not change any "condition established" in KVK's ANDA for Hydroxyzine; (2) even if it did, the FDA received

the required notice when UCB informed the FDA about the change via an update to the DMF that was incorporated by reference in KVK's ANDA; (3) the regulation is too vague to have provided Defendants with the fair notice required for such a violation to result in criminal liability; and (4) the alleged failure of KVK to provide its own, duplicate notice of UCB's change to Dr. Reddy's could not have transformed KVK's approved drug into an unapproved new drug.

First, under 21 C.F.R. § 314.70(a), KVK was only required to notify the FDA about changes "in each condition established in an approved NDA beyond the variations already provided for in the NDA." That notification requirement was not triggered here. The material provided by Dr. Reddy's was produced according to UCB's methods and specifications, and it was tested, released, and shipped by UCB from Belgium after UCB ensured that the final API was up to its specifications. UCB therefore remained the manufacturer of record for the API—as authorized in KVK's ANDA—despite UCB's delegation of the initial manufacturing steps to Dr. Reddy's in Mexico. *See* 21 C.F.R. § 207.1 (defining "manufacture" to include not just physical production, but also "manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process, including, for example, analytical testing of drugs for another registered establishment's drug"). It follows then that UCB's decision to utilize Dr. Reddy's did not qualify as a change to any "condition established in [KVK's] [A]NDA" and thus that KVK already had FDA's approval to distribute the Hydroxyzine.

Second, the FDA did receive notification of the switch to Dr. Reddy's. The Government cannot dispute that UCB provided advance notice of its intention to use Dr. Reddy's by filing an amendment to its DMF. That is the same DMF that KVK incorporated by reference in its ANDA. *See* 21 C.F.R. § 314.430(a) (providing that an ANDA "includes all data and information

. . . incorporated by reference in the . . . [ANDA], including . . . drug master files"). Despite this, the Government seeks to hold Mr. Panchal and his co-Defendants criminally liable based on essentially the failure to file a duplicate notice. The conspiracy statute does not reach so far.

Third, the rule of lenity should be applied because, even if the Court finds that there was a regulatory violation, the regulatory provision that Mr. Panchal is accused of violating falls far short of providing "fair warning of the conduct [it] prohibits or requires." *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012); *see also United States v. Harra*, 985 F.3d 196, 213 (3d Cir. 2021) (courts interpret ambiguous criminal statutes and regulations in the defendant's favor to ensure that an agency "clearly communicated its policies before a private party may be sanctioned—much less criminally prosecuted—for violating them"). The FDA did not "clearly communicate[] its policies" here. Indeed, in 2015, the FDA itself acknowledged the "confusion," "lack of clarity," and differing understandings as to what types of changes qualified as changes to an "established condition" in an ANDA and thus were required to be reported to the FDA. FDA, Established Conditions: Reportable CMC Changes for Approved Drugs and Biologic Products: Guidance for Industry 1 (May 2015). That confusion over reporting requirements perhaps explains, at least in part, why the FDA decided not to take any administrative action against Mr. Panchal or his co-Defendants at the time. The "lack of ascertainable certainty" about the scope of 21 C.F.R. § 314.70 should also preclude a criminal prosecution based on an alleged violation of that provision. *Harra*, 985 F.3d at 213.

Finally, even if the Government could establish that KVK's conduct violated FDA regulations, it cannot establish that KVK's failure to provide duplicate notice of UCB's use of Dr. Reddy's transformed KVK's approved Hydroxyzine into an "unapproved new drug." An ANDA "remains effective unless it is suspended," *Weinberger*, 412 U.S. at 633, and the FDA

never suspended KVK's ANDA for Hydroxyzine here. KVK therefore never lost its authorization to market Hydroxyzine pursuant to its ANDA. The manufacturer of record for the API remained UCB, and there was no change in any established condition in the ANDA for which pre-approval was required. Indeed, under the Government's theory, any technical reporting violation would automatically transform an approved drug into an unapproved new drug. That is not the law.

Based on the foregoing, and for the reasons stated more fully in KVK's Motion to Dismiss, the Court should find that the Indictment fails to state an offense as a matter of law.

B. <u>The charges against Mr. Panchal are time barred as a matter of law.</u>

The Court should also dismiss the Indictment as to Mr. Panchal because the charges are barred by the applicable statute of limitations. A conspiracy charge under 18 U.S.C. § 371 must be brought "within five years . . . after such offense shall have been committed." 18 U.S.C. § 3282. To satisfy the statute of limitations in connection with a conspiracy charge, the Government must demonstrate that "at least one overt act in furtherance of the conspiracy was performed" within five years of the date the indictment was returned. *Grunewald v. United States*, 353 U.S. 391, 396-97 (1957). "[T]he crucial question in determining whether the statute of limitations has run is the scope of the conspiratorial agreement, for it is that which determines both the duration of the conspiracy, and whether the act relied on as an overt act may properly be regarded as in furtherance of the conspiracy." *Id.* at 397.

A court may dismiss an indictment as untimely where it is established that the indictment charges conduct that occurred outside of the applicable statute of limitations period. *See, e.g.*, *United States v. Atiyeh*, 402 F.3d 354, 362 (3d Cir. 2005) (concluding that an indictment which, on its face, charged conduct occurring outside the five-year limitations period of 18 U.S.C. § 3282 was beyond the statute of limitations); *United States v. Musto*, No. 3:10-CR-338, 2012 WL

5879609, at *4 (M.D. Pa. Nov. 21, 2012) (granting motion to dismiss bribery charges as time barred on face of indictment).

i. The alleged goal of the conspiracy was achieved no later than December 2013 and thus the charges against Mr. Panchal are time barred as a matter of law.

In Count One, the Indictment alleges that Mr. Panchal participated in a conspiracy: (i) to impair, impede, and defeat the lawful functions of the FDA in ensuring that drugs distributed in the United States are safe and effective for their intended uses; and (ii) to commit an offense against the United States (a) by distributing Hydroxyzine during the period of April 2011 through December 2013 despite knowing that it was manufactured using API with material from an allegedly unapproved source, and (b) by taking various actions (or failing to take certain actions) intended to mislead the FDA about how the alleged regulatory violations came about. *See* Dkt. 4 at 6 ¶ 16; *id.* at 10 ¶ 9. Though Count One charges a single offense, there are two distinct theories: (1) that Defendants conspired to defraud the FDA and commit an offense against the United States by unlawfully distributing Hydroxyzine, and (2) that Defendants conspired to commit an offense against the United States by making false statements to deceive the FDA and prevent it from taking enforcement action against them. Said differently, Count One alleges a conspiracy to commit a crime (*id.* at 6 ¶ 16(a) & 6 ¶ 16(b)(1)) and subsequent actions to conceal the circumstances pertaining to that already-completed crime (*id.* at 6 ¶ 16(b)(2)).

To determine when the statute of limitations began running, the Court must determine when the "central criminal purposes" of the conspiracy were achieved. *See Grunewald*, 353 U.S. at 401-02 ("[A]fter the central criminal purposes of a conspiracy have been attained, a subsidiary conspiracy to conceal may not be implied from circumstantial evidence showing merely that the conspiracy was kept a secret and that the conspirators took care to cover up their crime in order

to escape detection and punishment."). Here, the "central criminal purpose" of the conspiracy charged in Count One was accomplished in December 2013, when KVK last distributed the allegedly unapproved Hydroxyzine. *See* Dkt. 4 at 10 ¶ 9 (alleging that "from in or about April 2011 through at least in or about December 2013, defendant KVK-TECH delivered to its customers approximately 62 batches of Hydroxyzine tablets made from unapproved HCL API"). It was at that point that the conspiracy no longer "subsisted" and the five-year statute of limitations began running. *See Grunewald*, 353 U.S. at 397.

The Government cannot extend the statute of limitations by reference to an implied subsequent conspiracy to avoid detection and punishment. *See id.* at 404 (rejecting "the proposition that the duration of a conspiracy can be indefinitely lengthened merely because the conspiracy is kept a secret, and merely because the conspirators take steps to bury their traces, in order to avoid detection and punishment after the central criminal purpose has been accomplished"); *United States v. Fattah*, 223 F. Supp. 3d 336, 353 (E.D. Pa. 2016), *aff'd in part, rev'd in part*, 902 F.3d 197 (3d Cir. 2018), *amended and superseded on reh'g*, 914 F.3d 112 (3d Cir. 2019), *and aff'd in part, rev'd in part*, 914 F.3d 112 (3d Cir. 2019) (Bartle, J.) ("Concealment activities after the purpose of the conspiracy has been attained 'for the purpose only of covering up after the crime' do not extend the time to file an indictment."); *United States v. Roshko*, 969 F.2d 1, 7 (2d Cir. 1992) (statute of limitations for conspiracy to commit immigration fraud began running on the date the defendant obtained a fraudulent green card and could not be extended by his subsequent divorce and marriage to another person because those actions were "superfluous to . . . [and] did not further the conspiracy's principal objective of altering [his] immigration status").

It is clear, however, that extending the statute by reference to alleged subsequent acts of concealment is precisely what the Government seeks to do. The handful of overt acts alleged in the time period of 2014 through 2015 relate to actions (or omissions) that Mr. Panchal and his co-Defendants purportedly took to mislead the FDA as to the circumstances underlying KVK's ***previous*** alleged unlawful distribution of Hydroxyzine in 2011 through 2013. *See* Dkt. 4 at 12-14 ¶¶ 15-19; *see also, e.g.*, *id.* at 13 ¶ 16 (alleging that Mr. Panchal misled the FDA at a June 27, 2014 meeting by "continu[ing] to promote the false narrative that a mistake by a former employee had caused the company to inadvertently manufacture and distribute Hydroxyzine containing the HCL API manufactured by DRL in Mexico"). There is no allegation that KVK unlawfully distributed Hydroxyzine after December 2013, much less that Mr. Panchal did anything in 2014 or 2015 to help achieve that goal. To the contrary, the alleged object of the conspiracy (the distribution of allegedly unapproved Hydroxyzine) had already been achieved no later than December 2013. Thus, any subsequent actions to mislead the FDA about that prior activity cannot extend the statute of limitations. *See Grunewald*, 353 U.S. at 396-97.

This is the precise situation that the *Grunewald* rule was intended to address. If the Government was allowed to extend the statute of limitations by reference to alleged subsequent acts of Mr. Panchal and his co-Defendants to avoid detection and punishment for the alleged unlawful distribution in 2011 through 2013, that would threaten to "extend the life of [the alleged] conspiracy indefinitely" and would risk "broaden[ing] the already pervasive and wide-sweeping nets of conspiracy prosecutions." *Id.* at 404.

In sum, the principal objective of the alleged conspiracy in Count One (the distribution of 62 batches of allegedly unapproved Hydroxyzine) was achieved no later than December 2013, and it was at that point that the five-year statute of limitations under 18 U.S.C. § 3283 began

running. Any alleged actions taken after that point to conceal the circumstances of an already-completed crime cannot serve to extend the statute of limitations. *See id.* at 396-97; *Fattah*, 223 F. Supp. 3d at 353; *Roshko*, 969 F.2d at 7. Because the Indictment was not filed within five years of December 2013—it was filed almost eight years later on June 20, 2021—it is untimely on its face and should be dismissed.

ii. Even if the alleged conspiracy extended beyond December 2013, the charges against Mr. Panchal would still be time barred.

Even if the Court views the conduct alleged in the Indictment as part of a single conspiracy that continued past December 2013, which it should not, the charges against Mr. Panchal would still be time barred.

1. The Indictment is time barred on its face.

The statute of limitations for a conspiracy charge begins to run on the date of the last overt act in furtherance of the conspiracy. *See Grunewald*, 353 U.S. at 396-97. Here, the last "overt act" alleged in the Indictment is that, "on or about March 2, 2015," the FDA released a Final Establishment Inspection Report ("EIR") and that Mr. Panchal "failed to notify the FDA of the falsehoods [in the EIR] . . . knowing the EIR was substantially false[.]" Dkt. 4 at 14 ¶ 19. Thus, assuming *arguendo* that an alleged omission could be a sufficient overt act in support of a conspiracy charge,[2] the Indictment must have been returned no later than March 2, 2020 to be timely.[3] The Indictment, however, was filed on June 10, 2021. It is therefore untimely on its face and should be dismissed.

[2] As discussed *infra* at 16-19, the Government cannot rely on Mr. Panchal's alleged failure to respond to the EIR as an overt act in support of the conspiracy charge. The Court should therefore decline to rely on March 2, 2015 as the date of the most recent overt act for purposes of its statute of limitations analysis.

[3] Mr. Panchal did not even receive a target letter until March 2020, notwithstanding the fact that the Government began investigating KVK as early as 2015. The fact that Mr. Panchal was not a

2. The Government's request for foreign evidence and execution of a tolling agreement with Mr. Panchal does not bring this case within the statute of limitations.

The Government will likely argue that the charges are timely based on two facts outside of the Indictment: (i) that it signed a tolling agreement with Mr. Panchal on June 8, 2020; and (ii) that the statute of limitations was tolled for a certain amount of time prior to that date based on its request for evidence from the Government of Belgium pursuant to a Mutual Legal Assistance Treaty ("MLAT"). Neither can bring this case within the statute of limitations. As discussed below, the five-year statute of limitations began running at the latest on November 20, 2014, and the Government is entitled to no more than six months of tolling in connection with its MLAT request. Thus, the statute ran no later than May 20, 2020 (five years and six months after November 20, 2014), which is ***before*** Mr. Panchal executed a tolling agreement with the Government on June 8, 2020. The charges against Mr. Panchal are therefore time barred.

a. The last possible overt act occurred, and the statute of limitations thus began running, on November 20, 2014.

i. The Government has failed to adequately allege an overt act that took place on March 2, 2015.

In the Indictment, the Government contends that the most recent "overt act" occurred on March 2, 2015, when Mr. Panchal purportedly failed to inform the FDA of unidentified alleged "falsehoods" in an EIR that the FDA issued to KVK at the end of an inspection. Dkt. 4 at 14 ¶ 19. Mr. Panchal's purported failure to correct alleged falsehoods in a report issued to his employer cannot serve as an overt act in support of a conspiracy charge.

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part of this case until such a late date further underscores the staleness of the charges against him and the prejudice he will suffer in being forced to defend against charges arising from events occurring, in some instances, almost a decade ago. *See infra* at 22-23.

The Government has not alleged any legal duty on the part of Mr. Panchal to take any action in response to the EIR. Nor does one exist. An EIR is a standard document prepared by the FDA at the conclusion of an inspection and did not request nor require that Mr. Panchal, a non-executive level employee of KVK, nor any other KVK employee for that matter, provide any kind of response. The EIR was simply a summary document prepared by the FDA detailing the findings and outcome of the inspection. *See United States v. John D. Copanos & Sons, Inc.*, 831 F.2d 466, 468 (4th Cir. 1987) (noting that EIRs "are narrative reports stating what occurred and what was undertaken during an FDA inspection"); *In re Digitek Prod. Liab. Litig.*, 821 F. Supp. 2d 822, 829 (S.D.W. Va. 2011) (noting that an EIR contains an "inspector's observations in terms of compliance with cGMPs" and that EIRs "are not typically made available to the [target of the investigation] and are not used as notification of conditions the investigator believes reflect a cGMP deficiency"). As such, there was no duty or expectation that Mr. Panchal would provide a response to the EIR, and his failure to do so therefore cannot be an overt act in furtherance of the alleged conspiracy.[4]

Moreover, there is no question that the Government believes that Mr. Panchal's intention in failing to correct the allegedly false EIR was to prevent the FDA from discovering the full scope of an alleged crime that had taken place previously, i.e. the unlawful distribution of Hydroxyzine in 2011 through 2013. *See* Dkt. 4 at 14 ¶ 19 (alleging that Mr. Panchal "failed to notify the FDA of the falsehoods [in the EIR] to avoid enforcement action or being required to

[4] Relying on Mr. Panchal's failure to correct alleged falsehoods in the EIR as an overt act would also raise constitutional concerns. If the Government is correct (which it is not) that there were falsehoods in the EIR, Mr. Panchal may well have exposed himself to criminal liability by attempting to correct those alleged falsehoods. Mr. Panchal was not required to implicate himself in a potential crime—*see* U.S. Const. amend. V (privilege against self-incrimination)—particularly where the Government can establish no duty on his part to take any action in response to an EIR that was issued to his employer.

perform needed corrective actions"). However, alleged inaction for the purpose of covering up a previous crime cannot constitute an overt act in support of the conspiracy charged in Count One, for the same reasons it cannot extend the statute of limitations—the central objective of the conspiracy had already been achieved no later than December 2013. *See, e.g.*, *Joseph M. v. Ne. Educ. Intermediate Unit 19*, 516 F. Supp. 2d 424, 448 (M.D. Pa. 2007), *on reconsideration*, No. CIV.A. 3:06-CV-01903, 2007 WL 2845004 (M.D. Pa. Sept. 26, 2007) (rejecting notion that "inaction by . . . co-conspirators is sufficient to satisfy the overt act requirement"); *Kirschner as Tr. of Millennium Lender Claim Tr. v. J.P. Morgan Chase Bank, N.A.*, No. 17CIV6334PGGSLC, 2020 WL 9815174, at *17–18 (S.D.N.Y. Dec. 1, 2020), *report and recommendation adopted sub nom. Kirschner as Tr. of Millennium Lender Claim Tr. v. JPMorgan Chase Bank, N.A.*, No. 17 CIV. 6334 (PGG), 2021 WL 4499084 (S.D.N.Y. Sept. 30, 2021) (holding that an "overt act" for purposes of a conspiracy claim "typically must be an affirmative act" and that "a failure to act or to disclose is insufficient"); *Heinert v. Bank of Am., N.A.*, 410 F. Supp. 3d 544, 553 (W.D.N.Y. 2019), *aff'd*, 835 F. App'x 627 (2d Cir. 2020) ("[A]llegations which concern inaction rather than overt acts, are insufficient to establish a conspiracy to defraud."); *cf. United States v. Bornman*, 559 F.3d 150, 154-55 (3d Cir. 2009), *as amended* (Apr. 24, 2009), *as amended* (May 5, 2009) (alleged failure to return purported bribe could not extend statute of limitations); *United States v. Davis*, 533 F.2d 921, 928 (5th Cir. 1976) ("The fact that the appellants never corrected the false statements contained in the contract proposal does not make the conspiracy charged in the indictment a continuing one, and thereby extend the statute of limitations.").

As such, the Government's allegation in Paragraph 19 (on Page 14) of the Indictment is insufficient to allege an overt act in furtherance of the charged conspiracy. The Court should

therefore decline to rely on March 2, 2015 as the date of the last overt act for purposes of its statute of limitations analysis.

ii. The Government has failed to adequately allege an overt act occurring on December 11, 2014.

The next overt act alleged by the Government is that "[o]n or about December 11, 2014, during another inspection conducted by the FDA . . . defendant ASHVIN PANCHAL provided a document to the FDA titled Manufacturing Deviations and Investigations Report (the 'MDI' Report')," which he knew "contained false and misleading information." Dkt. 4 at 13-14 ¶ 18. But the Government's own records show that Mr. Panchal provided the MDI Report at issue (also known as MDI Report 13/063) to the FDA first on January 15, 2014,[5] and again during an FDA inspection on ***November 20, 2014***. *See* Ex. A at 6 (excerpt from handwritten notes of FDA inspector).[6] Mr. Panchal did not provide this document to the FDA on December 11, 2014, and the Government will not be able to show otherwise. In fact, it appears that the Government simply took the date on which the inspection ended (i.e. December 11, 2014) and made the bald assertion that this is the date on which the MDI Report was provided. But that is plainly not so. The Court should find that the last possible alleged overt act in support of the conspiracy occurred on November 20, 2014, not December 11, 2014. As the statute of limitations for a

[5] Mr. Panchal provided this document to the FDA for the first time on January 15, 2014 as part of KVK's final Field Alert Report. Thus, the FDA was already in possession of this document as of January 15, 2014. Even assuming that providing the same report to the FDA months later could constitute a separate overt act, a concept which is questionable at best, the charges against Mr. Panchal are still time barred for the reasons discussed *infra*.

[6] The Court can consider such evidence on a motion to dismiss because the Government cannot dispute the authenticity of the FDA inspector's notes, which corroborate that Mr. Panchal provided the MDI Report to the FDA no later than November 20, 2014. *See, e.g.*, *United States v. Todd*, 446 F.3d 1062, 1068 (10th Cir. 2006) (a court may dismiss charges when undisputed facts show "as a matter of law, [that] the government is incapable of proving its case beyond a reasonable doubt").

conspiracy charge begins to run on the date of the last overt act in furtherance of the conspiracy, *see Grunewald*, 353 U.S. at 396-97, November 20, 2014 is also the date on which the Court should find that the statute of limitations began running.

b. The Government is entitled to no more than six months of tolling under 18 U.S.C. § 3292.

Under 18 U.S.C. § 3292, a statute of limitations may be tolled for no more than six months when the Government makes a request for evidence from a foreign government and the foreign government takes final action on the request before the statute of limitations otherwise would have expired. 18 U.S.C. § 3292(c)(2) ("The total of all periods of suspension under this section with respect to an offense . . . shall not extend a period within which a criminal case must be initiated for more than six months if all foreign authorities take final action before such period would expire without regard to this section."). Section 3292 therefore establishes a six-month cap on tolling in situations where a foreign government takes final action on an MLAT request prior to the natural running of a statute of limitations.

Here, the Government made a request for evidence from Belgium under an MLAT, and Belgium took final action on that request before the statute of limitations would have otherwise expired. Specifically, the Government made a request for evidence from Belgium on December 23, 2016, obtained a court order tolling the statute of limitations on February 28, 2017, and received responses from Belgium on January 8, 2018 and March 22, 2018. *See* Ex. B (Feb. 28, 2017 Order of Hon. Cynthia M. Rufe); Ex. C (correspondence from Belgian Government). The discovery provided by the Government reflects no further response from Belgium after March 22, 2018. Thus, the Court should find that March 22, 2018 is the date of "final action" pursuant to the MLAT. The statute of limitations would have expired in the natural course after the date of final action, on November 20, 2019 (i.e. five years after the last possible alleged overt act on

November 20, 2014).[7] As Belgium took final action on the Government's request prior to the date on which the statute would have otherwise expired, the six-month cap on tolling set forth in 18 U.S.C. § 3292(c)(2) applies. Thus, the Government is entitled to no more than six months of tolling pursuant to 18 U.S.C. § 3292(c)(2).

c. The statute of limitations ran prior to Mr. Panchal's execution of a tolling agreement and the charges are therefore time barred.

Based on the above, the Court should conclude that the statute of limitations has run as to Mr. Panchal. The last possible overt act in furtherance of the alleged conspiracy occurred on November 20, 2014.[8] The statute of limitations therefore would have naturally run five years later on November 20, 2019. Because the Government is entitled to no more than six months of tolling pursuant to 18 U.S.C. § 3292(c)(2), the statute of limitations is extended, at most, by six months to May 20, 2020. Mr. Panchal did not sign a tolling agreement with the Government until almost one month later, on June 8, 2020. As such, the tolling agreement is ineffective, and the charges against Mr. Panchal are time barred as a matter of law. *See* Ex. D at 1-2 (stating that Mr. Panchal "will not raise the statute of limitations as a defense in any criminal proceedings . . . ***except to the extent that the statute of limitations has already run or expired as of the date of this agreement***") (emphasis added).

[7] Even assuming *arguendo* that the statute of limitations runs from March 2, 2015 (which it does not, as discussed *supra*), the Government would still be limited to no more than six months of tolling. If the statute began running on March 2, 2015, it would have otherwise expired on March 2, 2020. Belgium's final action on the Government's request on March 22, 2018 occurred well before that date and, thus, the six-month cap on tolling in 18 U.S.C. § 3292(c)(2) would apply.

[8] Mr. Panchal maintains that the Government cannot rely on the same conduct—providing the MDI Report to the FDA—to support two separate overt acts. Mr. Panchal provided that report to the FDA for the first time on January 15, 2014, so it is Mr. Panchal's position that that is the date on which the overt act occurred. The Court need not resolve the issue, however, because even if the Court goes with the latest possible date (November 20, 2014), the charges are time barred.

d. The government's failure to bring this case within the statute of limitations has prejudiced Mr. Panchal.

The Government's failure to abide by the statute of limitations is not simply a technicality. It has caused, and will continue to cause, undue prejudice to Mr. Panchal. As it stands, Mr. Panchal is in the position of having to defend against felony charges arising from events occurring, in many instances, more than a decade ago. Indeed, the crux of the alleged wrongdoing in this case supposedly occurred in the 2010 through 2013 time period. *See* Dkt. 4 at 7 ¶ 1 (alleging that, on or about October 29, 2010, Mr. Vepuri "authorized the purchase of a non-returnable, commercial quantity of HCL API manufactured by Dr. Reddy's" despite knowing that KVK's "FDA-approved ANDAs did not include [Dr. Reddy's] as an HCL API manufacturer"); *id.* at 10 ¶ 9 (alleging that KVK delivered 62 batches of allegedly unapproved Hydroxyzine "[d]uring the period from in or about April 2011 through at least in or about December 2013"). Some allegations stretch back even farther in time. *See id.* at 5 ¶ 13 (alleging that, on or about May 31, 2008, Mr. Panchal notified the FDA that KVK "intended to obtain HCL API from" an Italian manufacturer). Despite the age of the allegations—and the fact that the Government had been investigating KVK since at least 2015—Mr. Panchal was not even notified that he was a target of the investigation until March 2020, more than five years after the end of the alleged conspiracy.

Statutes of limitations exist for the very purpose of protecting individuals such as Mr. Panchal from being held to defend against such stale allegations. *See, e.g.*, *United States v. Levine*, 658 F.2d 113, 123 (3d Cir. 1981) ("[A] central purpose of statutes of limitations [is] to prevent the government from instituting prosecutions after excessively long delays which may prejudice defendants by increasing the difficulty of marshalling evidence[.]"); *Toussie v. United States*, 397 U.S. 112, 114-15 (1970) (statutes of limitation are "designed to protect individuals

from having to defend themselves against charges when the basic facts may have become obscured by the passage of time and to minimize the danger of official punishment because of acts in the far-distant past"). Statutes of limitation also exist to safeguard the integrity of the judicial system as a whole, as they are "linked to protecting the truth and accuracy of the factfinding process at trial." *Levine*, 658 F.2d at 123. The truth and accuracy of the factfinding process would be in serious jeopardy here if the charges against Mr. Panchal are allowed to proceed. As time passes, "memories fade, witnesses become harder to locate or make themselves available, and evidence disappears." *CPIF Lending, LLC v. Chestnut Hill HCP I, LLC*, No. CV 18-2049, 2020 WL 3642479, at *2 (E.D. Pa. July 6, 2020); *see also Jackson v. City of Philadelphia*, No. CV 16-3892, 2019 WL 883989, at *7 (E.D. Pa. Feb. 22, 2019) (noting that "testimonial evidence disappears at the rate at which human memories fade" and finding prejudice where more than four years had passed since the events described in the plaintiff's complaint). Mr. Panchal's ability to prepare a defense to the charges has been hampered by the passage of time since the events described in the Indictment. The Government's delay in filing charges should not be excused.

The Court should find that the charges are time barred and dismiss the Indictment as to Mr. Panchal.

V. CONCLUSION

For the foregoing reasons, Mr. Panchal respectfully requests that the Court grant his Motion to Dismiss.

Respectfully submitted,

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December 1, 2021

CERTIFICATE OF SERVICE

I hereby certify that on December 1, 2021, I caused a true and correct copy of the foregoing Motion to Dismiss the Superseding Indictment and accompanying exhibits to be filed through the Court's electronic filing system (CM/ECF), which will then send notice of filing to all parties of record.

/s/ Patrick J. Egan
Patrick J. Egan